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(54) Title: **DEVICES**

(57) Abstract: A pre-formed, sheet device comprising; (a) less than 10 % of a polysaccharide mixture consisting of at least one red seaweed polysaccharide and at least one glucomannan; and (b) from about 30 % to about 99.5 % of water wherein the device comprises less than 10 % total polysaccharide. The pre-formed, sheet devices of the invention are suitable for topical application and display desirable amounts of syneresis and/or improved mechanical properties such as strength or flexibility, as well as excellent moisturisation, hydration and cooling benefits. Further, the devices of the present invention are easy to handle, unobtrusive and conform to the contours of a target surface when applied.

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Devices

Technical Field

The present invention relates to novel pre-formed, sheet devices and compositions thereof. In particular it relates to self-adhesive devices comprising an aqueous polysaccharide mixture, which are suitable for topical application and display desirable amounts of syneresis and/or improved mechanical properties such as strength or flexibility, as well as excellent moisturisation, hydration and cooling benefits. Further, the devices of the present invention are easy to handle, unobtrusive and conform to the contours of a target surface when applied. The desired properties are achieved by selecting the chemical composition and rheological characteristics of the polysaccharide mixture.

Background of the Invention

There exist numerous means of delivering beneficial agents to the skin, hair or nails such as by the use of creams, gels or lotions and the like. These forms are not always convenient to apply and do not provide a controlled release of a benefit agent to an area, or are inefficacious at delivering the intended benefits to the applied area due to external environmental factors. Further, some benefit agents are not stable in these aforementioned product forms resulting in difficulties in formulating compositions which remain chemically and physically stable.

In order to overcome the aforementioned inconveniences associated with creams and lotions and the like, the benefits of using a patch or other such device for the treatment of skin has been recognised in the art. A variety of cosmetic patches or devices are commercially marketed or described as being useful for the delivery of skin care actives such as vitamins, anti-acne actives, moisturisers and the like. Patches and devices have also been described in the literature and marketed in the medical field as a useful means for the transdermal administration of drugs. However, many of these patches or devices suffer drawbacks in their physical product forms resulting in undesirable in-use characteristics as perceived by the consumer or wearer. For example, EP-A-392,845 in one embodiment describes a method of preparation of a gel patch whereby the patch requires formation *in-situ* on the skin, making it messy to apply. EP-B-309,309 describes a dry patch which requires the skin to be moistened or the patch wetted so that it hydrates and adheres to the skin. Conversely, other patches or devices may be too wet or sticky, as the gelling agents comprising the patch or device may not form a solid gel structure and as a result, the patches or devices are difficult to handle and apply to the skin.

Some patches or devices are too dry, or are inflexible and therefore do not conform well to the contours of the surface to which they are applied. Alternatively, others may be strongly adhesive, tight and uncomfortable to wear and remove, and many patches may not provide an effective release and penetration of benefit agents.

Polysaccharide compositions are known for use in self adhesive patches or devices. For example EP-A-682 938, WO96/25923, EP-A-750905, WO98/17263, EP-A-850649, EP-A-674913 and WO84/02466 disclose various polysaccharides which may be useful in an adhesive patch or device. Additionally, many of the adhesive patches or devices described in the aforementioned documents optionally comprise cosmetic or therapeutic actives.

GB 1,341,999 discloses a gelled medium suitable for treating burns comprising a liquid phase, a burn treating agent and an amount of a gel former. The gelled medium is described as being flexible and having an essentially dry, continuous, non-adhesive surface and plasticity so as to conform to the body. The examples disclose a burn treating antiseptic pad comprising agarose, water and silver nitrate. The document discusses that a slight amount of syneresis in the gelled medium is helpful in wetting the surface with the burn treating substance and for ease in removal of the medium from a mould.

JP-A- 54 92618 discloses a wet compress comprising an aqueous calcium ion cross-linked alginate gel as a base, substances having an antiphlogistic and analgesic action and water. Example 5 discloses a wet compress comprising a mixture of locust bean gum, konjac powder, a 3% sodium alginate solution, a calcium monohydrate phosphate source and a styrene-butadiene copolymer latex. The document teaches that the addition of water soluble polymers increases the shape retaining power of a compress and a highly elastic gel is obtained by adding locust bean gum and konjac mannan, or carrageenan alone. However, the addition of water soluble polymers such as konjac and locust bean gum, amongst others, to the wet compress is taught as impeding the release of water. Further, the base containing gels of the wet compresses of the invention are taught as not being liable to release water.

While the patches and devices from the cosmetic and medical field art provide advances in attaining desirable physical and in-use characteristics from a polysaccharide gel, they do not teach devices comprising the specific aqueous polysaccharide mixtures of the present invention which have improved mechanical properties and/or which display a desirable amount of syneresis so as to provide a patch or device which is self adhesive and which effectively releases the ingredients comprised within the polysaccharide matrices

such as benefit agents and water to deliver in-use hydration, moisturisation or treatment benefits.

It has now been surprisingly found that less than 10% of an aqueous polysaccharide mixture consisting of at least one red seaweed polysaccharide and at least one glucomannan, provides a pre-formed, sheet device with excellent in-use characteristics, and improved syneresis, and/or mechanical properties. Devices comprising the aforementioned aqueous polysaccharide mixture form a self supporting, sheet device which has a high flexibility to conform to the contours of the skin, hair or nails, is thin, yet forms a high strength structure which is easy to handle and apply to the target surface. The aqueous polysaccharide mixture is selected to further provide the pre-formed, sheet device with a desirable amount of syneresis.

Summary of the Invention

The present invention relates to a pre-formed, sheet device comprising;

- (a) less than 10% of a polysaccharide mixture consisting of at least one red seaweed polysaccharide and at least one glucomannan; and;
- (b) from about 30% to about 99.5% of water

wherein the device comprises less than 10% total polysaccharide.

The pre-formed, sheet devices of the present invention show a desirable amount of syneresis, as well as providing excellent in-use characteristics such as unobtrusiveness, ease of handling, conformability, hydration, moisturisation and cooling benefits upon topical application. Further, the pre-formed, sheet devices of the present invention have excellent mechanical properties and form a high strength structure from a thin aqueous polysaccharide mixture which has a degree of elasticity and is flexible.

According to a second aspect of the present invention there is provided a cosmetic method of treatment comprising applying to the skin, hair or nails a pre-formed, sheet device.

According to a third aspect of the present invention there is provided a use of a polysaccharide mixture consisting of at least one red seaweed polysaccharide and at least one glucomannan, for improving the strength, syneresis or flexibility of a pre-formed, sheet device comprising water.

Detailed Description of the Invention

The pre-formed, sheet device of the present invention comprises a specified polysaccharide mixture together with water, as well as various optional ingredients as

indicated below. All levels and ratios are by weight of total composition of the device unless otherwise indicated. When a substrate is used as an adjunct to the device, the total weight of the composition of the device is calculated without including the weight of the substrate.

The term "pre-formed" as used herein, means that the device so described is manufactured into a product form having a predetermined thickness, shape and size, wherein the device may be removed from the packaging and placed or draped onto the target surface by the fingers without the need to spread, rub or coat the target area with the product form.

The term "sheet device", as used herein, means that the device described is a patch or mask for cosmetic or medical application having a planar or non-planar topography, wherein the patch is a continuous, uni-, bi-, or multi- lamellar sheet, and the shape of which is pre-determined according to the specific area of skin, hair or nails to be treated and wherein the mask is a non-continuous, uni-, bi-, or multi- lamellar sheet covering the facial area with apertures for the eyes, nose or mouth.

The term "syneresis" as used herein, means the process whereby a gel contracts on standing with the exudation of liquid. Without being limited by theory, it is believed that gel compositions form 3-dimensional matrices which bind or encapsulate other ingredients of the composition. Syneresis is believed to involve a spontaneous separation of an initial homogeneous system into a coherent gel phase and a liquid. The exuded liquid is a solution whose composition depends upon that comprised in the original gel. When a device of the present invention is applied to a target area, the device loses some of its volume such that ingredients bound within the gel matrices such as water or benefit agents, are released towards, and penetrate the target area.

The term "polysaccharide" as used herein, means a naturally occurring or synthetically produced, linear or branched polymer of monosaccharide units, which swells when dispersed in water at low dry concentrations and gels the aqueous phase.

The term "non-occlusive" as used herein, means that the pre-formed, sheet device as so described does not substantially block the passage of air and moisture through the surface of the skin, hair or nails.

The present pre-formed, sheet devices are suitable for topical application to the skin, hair or nails.

Polysaccharide Mixture

As an essential component of the pre-formed, sheet devices described herein, the devices comprise a specified polysaccharide mixture.

The polysaccharide mixture of the present invention forms a self-adhesive, sheet device which is self-supporting. Optionally, in order to improve the integrity of the device, an occlusive or non-occlusive backing material, often referred to as a "substrate" may be employed as an adjunct to the device. In order to impart added strength to the pre-formed, sheet devices, substances which act as gel strengthening agents such as mono- or multi-valent salts may be incorporated into the polysaccharide mixture. Suitable cations for the mono- or multi- valent salts may be selected from potassium, sodium, ammonium, zinc, aluminium, calcium and magnesium ions, or mixtures thereof. Suitable anions associated with the aforementioned cations may be selected from chloride, citrates, sulfate, carbonate, borate and phosphate anions, or mixtures thereof. If multi- or mono- valent salts are employed, generally, the pre-formed, sheet devices of the present invention comprise less than 4%, preferably less than 3% and more preferably less than 2% by weight of a salt.

It has been found that specific blends of polysaccharides in combination with water, form gels having desirable aesthetics and in-use characteristics. Further, the polysaccharides of the mixture of the present invention, may be combined together at various percentages or ratios to modify the physical characteristics of the pre-formed, sheet devices. The polysaccharide mixture herein provides improved syneresis, or mechanical properties, such as flexibility or strength, from the aqueous, pre-formed, sheet device. In a preferred embodiment, the polysaccharide mixture of the present invention improves the flexibility, strength, and syneresis of a pre-formed, sheet device.

The pre-formed, sheet devices of the present invention comprise less than 10% total polysaccharide. In general, the pre-formed, sheet devices of the present invention preferably comprise less than 10%, more preferably less than 5% and especially less than 2% and preferably greater than 0.5%, more preferably greater than 0.7%, by dry weight of the polysaccharide mixture.

The polysaccharide mixture of the devices herein consists of at least one red seaweed polysaccharide and at least one glucomannan.

Red Seaweed Polysaccharides: Polysaccharides which are classified as red seaweed polysaccharides are isolated from marine plant species belonging to the class of *Rhodophyceae*. Red seaweed polysaccharides provide mechanical strength to an aqueous

gel. Suitable red seaweed polysaccharides for use in the present invention include agar known in the industry under the (CTFA) trade designation as agar agar flake derived from various *Gelidium* plant species or closely related red algae commercially available as "Agar Agar 100" or "Agar Agar 150" from TIC Gums (Belcamp, MD, USA) or "Agar Agar K-100" from Gumix International Inc. (Fort Lee, NJ, USA); agarose commercially available as "Sea Plaque®" from FMC (Philadelphia, PA, USA) and "Agarose Type 1-b" from Sigma - Aldrich Co. Ltd. (Poole, UK); carrageenan, comprising the fractions lambda-, iota- and kappa- which are the water extracts obtained from various members of the *Gigartinales* or *Solieriales* families, known in the industry under the (CTFA) trade designation as chondrus, commercially available as "Gelcarin® LA", "Seakem® 3/LCM", or "Viscarin® XLV", all from FMC (Philadelphia, PA, USA); and furcellaran commercially available from Gum Technology Corporation (Tucson, Arizona, USA) and Continental Colloids Inc. (Chicago, IL, USA), or mixtures thereof. Preferably, the red seaweed polysaccharide for use herein is selected from agar, agarose, kappa-carrageenan and furcellaran, or mixtures thereof. More preferably, the red seaweed polysaccharide for use herein is selected from kappa-carrageenan and furcellaran, or mixtures thereof.

As has already been indicated, carrageenan is not a chemically homogeneous product, but comprises the product group of sulfated galactans, with a proportion of the galactopyranose residues being present as a 3,6-anhydrogalactose residue. Certain fractions of carrageenans can be isolated from red algae extracts which are chemically defined with respect to their structure and are designated by Greek letters. Only lambda-, iota-, and kappa-carrageenan are of commercial importance. Their different properties are principally explicable in terms of differences in the content of anhydrogalactose and sulfate ester groups. Moreover, the presence of the sulfate groups has the consequence that the properties of carrageenan as an anionic polysaccharide can be modified by the presence of cations in the aqueous system. Thus, the gelling properties of kappa-carrageenan are greatly influenced by potassium ions and those of iota-carrageenan by calcium ions.

On the other hand, agar, an electrically neutral galactan having a high anhydrogalactose content, gels independently of the addition of cations. Kappa-carrageenan has the highest anhydrogalactose content and the lowest sulfate content among the carrageenans and as a result has the most powerful gel-forming properties.

Glucomannan: Glucomannans are mannose containing polysaccharides which comprise an essentially linear backbone of β (1 \rightarrow 4)-linked glucose and mannose residues. The C-6 position of a mannose or glucose residue in the polysaccharide backbone may be

substituted with an acetyl group. The acetyl groups are generally found on one per six sugar residues to one per twenty sugar residues. Suitable glucomannans or derivatives thereof for use herein have a ratio of mannose to glucose of from about 0.2 to about 3. Preferred glucomannans for use herein include konjac mannan, which is the generic name for the flour formed from grinding the tuber root of the *Amorphophallus konjac* plant (elephant yam), commercially available under the trade name "Nutricon® konjac flour" from FMC (Philadelphia, PA, USA); and deacetylated konjac mannan; or mixtures thereof.

It is believed that in polysaccharide mixtures comprising a glucomannan, the mannose containing polysaccharide complements the red seaweed polysaccharide. This synergy is believed to arise due to the interactions between the polysaccharides. Red seaweed polysaccharides form double helical structures whereas glucomannans have areas of relative un-substitution on the polymer backbone. These areas of relative un-substitution, interact with the helices of the red seaweed polysaccharides and contribute to the mechanical strength and flexibility of the pre-formed, sheet devices of the present invention.

All gels undergo syneresis, as herein before defined, to some degree. Syneresis provides a mechanism for the delivery of a benefit agent to a target area. The liquid layer exuded onto the surface of the coherent gel phase is readily available for diffusion, facilitating a short wear time of the device. The pre-formed, sheet devices of the present invention desirably display a moderate amount of syneresis and preferably, the devices herein are moist to the touch. A moderate amount of syneresis is seen by the present inventors as a highly desirable property of a device comprising the polysaccharide mixture as the liquid exuded onto the surface of the gelled device facilitates its adhesion to a target surface thus obviating the need for either an additional adhesive overlaying the gelled form or an adhesive coated substrate. By comparison, if a gelled device exhibits too little syneresis, the device although wetting an area, is not likely to provide good adhesion to the target area, whilst an excessive amount of syneresis results in an ineffective and unattractive product.

From the viewpoint of providing improved syneresis and mechanical properties from a pre-formed, sheet device, preferably, the ratio of red seaweed polysaccharide to glucomannan is from about 5:1 to about 1:5 and more preferably from about 2:1 to about 1:2.

Water

A further essential ingredient of a pre-formed, sheet device of the present invention is water. The total water content of a pre-formed, sheet device of the present invention is from about 30% to about 99.5%, preferably from about 40% to about 95%, more preferably from about 50% to about 85% by weight of the device.

Substrate

In a preferred embodiment of the present invention, the pre-formed, sheet devices herein comprise a substrate. A substrate is an occlusive or non-occlusive sheet that provides additional integrity and support to the device.

Preferably the substrate is non-occlusive. The liquid, aqueous polysaccharide mixture may be coated or cast onto one surface of a substrate.

A wide variety of materials can be used as the substrate. The following characteristics are desirable: (i) sufficient wet strength for use, (ii) sufficient flexibility, (iii) sufficient loft and porosity, (iv) sufficient thickness, (v) sufficient hydrophilicity such that the polysaccharide gel mixture may diffuse and infiltrate into the substrate, (vi) sufficient compatibility with the polysaccharide mixture to prevent de-lamination, (vii) sufficient transparency or translucency, and (viii) appropriate size.

Non-limiting examples of suitable substrates meeting the above criteria include woven and nonwoven materials; polymeric sheet materials such as apertured formed thermoplastic films, formed films, apertured plastic films, and hydroformed thermoplastic films; natural sponges; synthetic sponges; polymeric mesh sponge; paper substrates; polymeric porous foams; collagen sheets; polymeric scrims and the like. Preferred substrates for use herein are paper substrates, nonwoven materials and formed films especially apertured formed films since they are economical and readily available in a variety of materials.

By nonwoven is meant a manufactured sheet, web, mat, pad or batt of directionally or randomly oriented fibers, bonded by friction, and/or cohesion and/or adhesion. These materials generally exclude products which are woven, knitted, tufted, stitch-bonded incorporating binding yarns or filaments, or felted by wet-milling, whether or not additionally needed. The nonwoven materials can be composed of a combination of layers of random and carded fibers. The fibers may be of natural or synthetic origin. Further, they may be staple or continuous filaments or be formed *in situ*.

Non-woven materials may be comprised of a variety of fibers both natural and synthetic. By natural is meant that the fibers are derived from plants, animals, insects or byproducts of plants, animals, and insects. By synthetic is meant that the fibres are obtained primarily from various man-made materials or from natural materials which have been further

altered. The conventional base starting material is usually a fibrous web comprising any of the common synthetic or natural textile-length fibers, or mixtures thereof.

Natural fibers useful in the present invention are silk fibers, keratin fibers such as wool fibers, camel hair fibers, and the like and cellulosic fibers including wood pulp fibers, cotton fibers, hemp fibers, jute fibers, flax fibers, and mixtures thereof.

Synthetic fibers useful in the present invention include acetate fibers, acrylic fibers, cellulose ester fibers, modacrylic fibers, polyamide fibers, polyester fibers, polyolefin fibers, polyvinyl alcohol fibers, rayon fibers, polyurethane foam, and mixtures thereof. Specific examples of some of these synthetic fibers and other suitable fibres and non woven materials prepared therefrom are described in WO98/18444, incorporated herein by reference, and include acrylics such as acrilan, creslan, and the acrylonitrile-based fiber, orlon; cellulose ester fibers such as cellulose acetate, arnel, and acele; and polyamides such as nylons (e.g., nylon 6, nylon 66, nylon 610, and the like).

Methods of making nonwoven materials are well known in the art and are described generally in WO98/18444, which is incorporated herein by reference. In the present invention the nonwoven layer can be prepared by a variety of processes including hydroentanglement, air entanglement, thermally bonding or thermo-bonding, and combinations of these processes. Moreover, the substrates of the present invention can consist of a single layer or multiple layers. In addition, a multilayered substrate can include films and other nonfibrous materials.

Nonwoven materials made from synthetic fibers useful in the present invention can also be obtained from a wide variety of commercial sources. Examples of suitable nonwoven layer materials useful herein are described in WO98/18444 and include HEF 40-047, an apertured hydroentangled material containing about 50% rayon and 50% polyester, and having a basis weight of about 51 grams per square metre (gsm), available from Veratec, Inc., Walpole, MA; Novonet^R 149-616, a thermo-bonded grid patterned material containing about 100% polypropylene, and having a basis weight of about 60 gsm, available from Veratec, Inc., Walpole, MA; and HEF Nubtex^R 149-801, a nubbed, apertured hydroentangled material, containing about 100% polyester, and having a basis weight of about 84 gsm, available from Veratec, Inc. Walpole, MA.

Paper substrates made from natural materials consist of webs or sheets most commonly formed on a fine wire screen from a liquid suspension of the fibers. See C.A. Hampel et al., The Encyclopedia of Chemistry, third edition, 1973, pp. 793-795 (1973); The Encyclopedia Americana, vol. 21, pp. 376-383 (1984); and G.A. Smook, Handbook of Pulp and Paper Technologies, Technical Association for the Pulp and Paper Industry (1986); which are incorporated by reference herein in their entirety. Paper substrates made

from natural materials useful in the present invention can be obtained from a wide variety of commercial sources. Suitable commercially available paper substrates useful herein include "Kimwipes EX-L" available from Kimberley-Clark Corp., Roswell, GA, USA; Airtex^R, an embossed airlaid cellulosic layer having a base weight of about 85 gsm, available from James River, Green Bay, WI; and Walkisoft^R, an embossed airlaid cellulosic having a base weight of about 90 gsm, available from Walkisoft U.S.A., Mount Holly, NC.

Alternately, the substrate can be a polymeric sheet material. Non-limiting examples of which include apertured formed thermoplastic films, formed films, apertured formed films, apertured plastic films and hydroformed thermoplastic films. Polymeric sheet materials may be prepared by methods well-described in the patent literature. For example, according to the process described in US-A-4,324,246, to Mullane and Smith, issued Apr. 13, 1982, a sample of thermoplastic material such as 0.0038 cm thick polyethylene film is heated above its softening point which is the temperature at which the thermoplastic material can be formed or moulded and is less than the melting point of the material. The heated thermoplastic material sheet form is then brought into contact with a heated forming screen. The forming screen is preferably an apertured wire mesh screen having the desired aperture size, pattern, and configuration. A vacuum is used to draw the heated film against the forming screen. A film is thereby formed against this screen with a desired pattern and hole size. While the vacuum is still being applied to the film, a jet of hot air is passed over the film. The hot air jet perforates the film in pattern and size of apertures in the forming screen. Fluid-permeable sheets prepared in the manner of the Mullane *et al* patent are conveniently referred to as "formed films". These sheet materials may also be made using a similar process method using a jet of water passed over the film. These materials are commonly referred to as "hydroformed films". A further example of such a material is described in US-A-4,609,518 to Curro *et al*, issued September 2, 1986, incorporated herein by reference in its entirety.

Another formed-film substrate useful herein is an apertured formed film - a resilient, 3-dimensional web exhibiting a fiber-like appearance and tactile impression, comprising a fluid-impervious plastic material, with said web having a multiplicity of apertures, the apertures being defined by a multiplicity of intersecting fiberlike elements, as described in US-A-4,342,314, to Radel and Thompson, issued Aug. 3, 1982, incorporated herein by reference. The sheet materials described in US-A-4,342,314 can be prepared using hydrophobic plastics such as polyethylene, polypropylene, PVC, and the like, and are well-known for use in absorbent products such as catamenials and the like. An example of such a material is the formed film described in the above patent and marketed on

sanitary napkins by The Procter and Gamble Company as "DRI-WEAVE". Additionally, such materials may be surface treated to reduce their hydrophobicity.

Alternatively, the substrate can be a polymeric mesh sponge as described in EP-A-702550 and WO98/18444 incorporated by reference herein in their entirety.

The substrate may also be a polymeric porous foam as described in US-A-5,260,345, to DesMarais, et al., issued Nov. 9, 1993, and US-A-4,394,930, to Koroman, issued July 26, 1983, incorporated herein by reference. Polymeric foams can in general be characterized as the structures which result when a relatively monomer-free gas or relatively monomer-free liquid is dispersed as bubbles in a polymerizable monomer-containing liquid, followed by polymerization of the polymerizable monomers in the monomer-containing liquid which surrounds the bubbles. The resulting polymerized dispersion can be in the form of a porous solidified structure which is an aggregate of cells, the boundaries or walls of which cells comprise solid polymerized material. The cells themselves contain the relatively monomer-free gas or relatively monomer-free liquid which, prior to polymerization, had formed the "bubbles" in the liquid dispersion. Specifically, soft, flexible, microporous (open or closed-cell) foam materials having surface hydrophilicity and fluid retention characteristics are particularly suitable for this application. Examples of polymeric foam materials are those prepared by polymerizing a particular type of water-in-oil emulsion. Such an emulsion is formed from a relatively small amount of a polymerizable monomer-containing oil phase and a relatively larger amount of a relatively monomer-free water phase. The relatively monomer-free, discontinuous "internal" water phase thus forms the dispersed "bubbles" surrounded by the continuous polymerizable monomer-containing oil phase. Subsequent polymerization of the monomers in the continuous oil phase forms the cellular foam structure. The aqueous liquid remaining in the foam structure formed upon polymerization can be removed by pressing and/or drying the foam. This type of polymerisation emulsion is generally known in the art as a high internal phase emulsion or "HIPE" foam.

Polymeric porous foams, including the foams prepared from the water-in-oil emulsions herein, may be relatively closed-celled or relatively open-celled in character, depending upon whether and/or the extent to which, the cell walls or boundaries, i.e., the cell windows, are filled or taken up with polymeric material. The polymeric porous foams useful in the present invention are those which are relatively open-celled in that the individual cells of the foam are for the most part not completely isolated from each other by polymeric material of the cell walls. Thus the cells in such substantially open-celled foam structures have intercellular openings or "windows" which are large enough to permit ready fluid transfer from one cell to the other within the foam structure.

In substantially open-celled structures of the type useful herein the foam will generally have a reticulated character with the individual cells being defined by a plurality of mutually connected, three dimensionally branched webs. The strands of polymeric material which make up the branched webs of the open-cell foam structure can be referred to as "struts." In addition to being open-celled, preferably, polymeric porous foams useful herein are hydrophilic in character.

The polymeric porous foams herein should be sufficiently hydrophilic such that the polysaccharide gel mixture may diffuse and infiltrate into the substrate and be sufficiently compatible with the polysaccharide mixture to prevent de-lamination. Although polymeric porous foams as herein before described are designed to be used in various fluid handling articles such as diapers, catamenials and incontinent devices, these types of materials are useful as a substrate in the present invention.

In another example, a suitable porous substrate material can be made from forming a thin, flexible, porous collagen sheet using a freeze-drying process. This process creates a sheet of collagen material which possesses the internal structures of an open-celled porous foam. These materials are strong, flexible, highly compatible with the polysaccharide gel, and have sufficient transparency or translucency to be appropriate as a substrate in the present invention. Examples of suitable commercially available collagen sheets useful herein include "Collagen Fiber Mask" available from Beauté Attica, Inc., Redmond, WA, USA; "Professional Collagen Masks" available from Luminescence, Maple Plain, MN, USA; "Pure Soluble Collagen Lifting Masque" available from Five Star Formulators, Inc., Palo Alto, CA, USA; and "Pure Collagen Masks" available from Maybrook, Inc., Lawrence, MA, USA.

The substrate can also be a polymeric scrim (extruded netting) as described in US-A-5,715,561, to Tuthill, Yeazell, and Girardot, issued Feb. 10, 1998, incorporated herein by reference. Polymeric scrims may be tubular and the properties of these polymeric scrims can be described by the physical dimensions of the resulting structure (node width, strand length, and repeat unit average weight). The tubular scrim material can have mesh openings shaped as a diamond, square, hexagon or other shape and can be made from a variety of strong flexible polymers such as low density polyethylene. For example, a diamond mesh scrim is plastic netting made by an extrusion process using counter-rotating die heads, each of which has multiple extrusion orifices located at the edge of each die. The counter rotation of the die heads causes extruded filaments or strands to align in two directions at angles to the machine direction of the extruded tubing. The strands periodically intersect to form nodes. The two strand directions are typically at acute angles to each other, such that strands form diamond patterns with nodes at each

corner. US-A-3,957,565 to Livingston *et al.* describes this process in more detail. Although these polymeric scrims (extruded netting) are designed to be used as a personal cleansing implement, these types of scrims can be used as a substrate in the present invention.

The substrate can be made into a wide variety of shapes and forms including flat pads, thick pads, thin sheets, and having sizes ranging from a surface area of about 0.25 cm² to about 1,000 cm². The exact size and shape will depend upon the desired use and product characteristics. Especially convenient are shapes which are designed to fit comfortably and conveniently to the users face, neck, hands, feet, and other parts of the body. These shapes may be square, circular, triangular, rectangular, oval, or other shapes which are composites of these such as shapes that could be described as "pickle", "butterfly", "moon", "semi-circle", "donut", or others.

The substrates of the present invention can comprise two or more layers, each having different textures. The differing textures can result from the use of different combinations of materials or from the use of different manufacturing processes or a combination thereof. In addition, separate layers of the substrate can be manufactured to have different colors, thereby helping the user to further distinguish the surfaces.

Benefit Agents

In a further preferred embodiment of the present invention, the pre-formed, sheet devices herein comprise a safe and effective amount of one or more benefit agents.

The term "safe and effective amount" as used herein, means an amount of a benefit agent high enough to modify the condition to be treated or to deliver the desired skin, hair or nail benefit, but low enough to avoid serious side effects, at a reasonable benefit to risk ratio within the scope of sound medical judgement. What is a safe and effective amount of the benefit agent will vary with the specific agent, the ability of the agent to penetrate through the skin, into, or onto the hair and/or nails, the user's age, the user's health condition, and the condition of the skin, hair or nails of the user, and other like factors.

The benefit agents include their pharmaceutically-acceptable salts and by "pharmaceutically-acceptable salts" are meant any of the commonly-used salts that are suitable for use in contact with the tissues of humans without undue toxicity, irritation, incompatibility, instability, irritation, allergic response, and the like.

In general, the pre-formed, sheet devices of the present invention comprise from about 0.01% to about 40%, preferably from about 0.05% to about 30% and most preferably

from about 0.1% to about 20% by weight of the device of at least one benefit agent, or mixtures thereof.

The benefit agents useful herein can be categorised by their therapeutic benefit or their postulated mode of action. However, it is to be understood that the benefit agents useful herein can in some instances provide more than one therapeutic benefit or operate via more than one mode of action. Therefore, classifications herein are made for the sake of convenience and are not intended to limit the benefit agent to that particular application or applications listed. The following benefit agents are useful in the pre-formed, sheet devices of the present invention.

Anti-Acne Actives: Anti-acne actives can be effective in treating and preventing *acne vulgaris*, a chronic disorder of the pilosebaceous follicles. The condition involves inflammation of the pilosebaceous apparatus thereby resulting in lesions, which may include papules, pustules, cysts, comedones, and severe scarring. The bacteria *Corynebacterium acnes* and *Staphylococcus epidermis* are usually present in the pustular contents. Examples of useful anti-acne actives include the keratolytics described in WO98/18444. Further useful actives include retinoids such as retinoic acid (e.g., cis and/or trans) and its derivatives (e.g., esters); retinol and its esters (e.g., retinyl propionate, retinyl acetate); abietic acid, adapalene, tazarotene, allantoin, aloe extracts, arbutic acid and its salts, ASEBIOL (available from Laboratories Serobiologiques located in Somerville, NJ), azaleic acid, barberry extracts, bearberry extracts, belamcanda chinensis, benzoquinolinones, benzoyl peroxide, berberine, BIODERMINE (available from Sederma located in Brooklyn, NY), bioflavonoids as a class, bisabolol, s-carboxymethyl cysteine, carrot extracts, cassia oil, clove extracts, citral, citronellal, climazole, COMPLETECH MBAC-OS (available from Lipo, located in Paterson, NJ), CREMOGEN M82 (available from Dragoco, located in Totowa, NJ), cucumber extracts, dehydroacetic acid and its salts, dehydroepiandrosterone and its sulfate derivative, dichlorophenyl imidazoldioxolan, d,l-valine and its esters, DMDM hydantoin, erythromycin, escinol, ethyl hexyl monoglyceryl ether, ethyl 2-hydroxy undecanoate, farnesol, farnesyl acetate, geraniol, geranyl geraniol, glabridin, gluconic acid, gluconolactone, glyceryl monocaprinate, glycolic acid, grapefruit seed extract, gugu lipid, HEDERAGENIN (available from Maruzen located in Morristown, NJ), hesperitin, hinokitol, hops extract, hydrogenated rosin, 10-hydroxy decanoic acid, ichthyol, interleukin 1 alpha antagonists, KAPILARINE (available from Greentech, located in Saint Beauzire, France), ketoconazole, lactic acid, lemon grass oil, LOCHOCHALCONE LR15 (available from Maruzen located in Morristown, NJ), linoleic acid, LIPACIDE C8CO (available from Seppic located in Paris, France),

lovastatin, 4-methoxysalicylic acid, metronidazole, minocycline, mukurossi, neem seed oil, niacinamide, nicotinic acid and its esters, nisin, panthenol, 1-pentadecanol, peonia extract, peppermint extract, phelladendron extract, 2-phenyl-benzothiophene derivatives, phloretin, PHLOROGINE (available from Secma located in Pontrieux, France), phosphatidyl choline, proteolytic enzymes, quercetin, red sandalwood extract, rosemary extract, rutin, sage extract, salicin, salicylic acid, serine, skull cap extract, siber hegner extract, siberian saxifrage extract, silicol, sodium lauryl sulfate, sodium sulfoacetamide, SOPHORA EXTRACT (available from Maruzen located in Morristown, NJ), sorbic acid, sulfur, sunder vati extract, tea tree oil, tetra hydroabietic acid, threonine, thyme extract, tioxelone, tocopherol and its esters, trehalose 6-undecylenoate, 3-tridecene-2-ol, triclosan, tropolone, UNTRIENOL T27 (available from Unichem, located in Chicago, IL), vitamin D₃ and its analogs, white thyme oil, willow bark extract, wogonin, ylang ylang, zinc glycerolate, zinc linoleate, zinc oxide, zinc pyrithione, zinc sulfate, zwitterionic surfactants (e.g., cetyl dimethyl betaine) and mixtures thereof.

Non-Steroidal Anti-Inflammatory Actives (NSAIDS): Examples of suitable NSAIDS and their esters for use herein are described in WO98/18444, incorporated herein by reference. Further non-limiting examples of non-steroidal anti-inflammatory drugs (NSAIDS) include flufenamic acid; panthenol and ether and ester derivatives thereof e.g. panthenol ethyl ether, panthenyl triacetate; pantothenic acid and salt and ester derivatives thereof, especially calcium pantothenate; aloe vera, bisabolol, allantoin and compounds of the liquorice (the plant genus/species Glycyrrhiza glabra) family, including glycyrrhetic acid, glycyrrhizic acid, and derivatives thereof e.g. salts such as ammonium glycyrrhizinate and esters such as stearyl glycyrrhetinate.

Topical Anaesthetics: Examples of suitable topical anaesthetic drugs for use herein are benzocaine and bupivacaine. Further suitable examples are described in WO98/18444, incorporated herein by reference.

Artificial Tanning Agents and Accelerators: Artificial tanning agents can help in simulating a natural suntan by increasing melanin in the skin or by producing the appearance of increased melanin in the skin. Non-limiting examples of artificial tanning agents and accelerators include glucose tyrosinate and acetyl tyrosine, brazilin, caffeine, coffee extracts, DNA fragments, isobutyl methyl xanthine, methyl xanthine, PHOTOTAN (available from Laboratoires Serobiologiques located in Somerville, NJ), prostaglandins, tea extracts, theophylline, UNIPERTAN P2002 (available from Unichem, located in Chicago, IL) and UNIPERTAN P27 (available from Unichem, located in Chicago, IL);

and mixtures thereof. Further useful artificial tanning agents herein are described in WO98/18444.

Antiseptics: Examples of suitable antiseptics for use herein include alcohols, benzoate, sorbic acid, and mixtures thereof.

Anti-microbial and Anti-fungal Actives: Anti-microbial and anti-fungal actives can be effective to prevent the proliferation and growth of bacteria and fungi. Non-limiting examples of antimicrobial and antifungal actives include ketoconazole, ciclopirox, benzoyl peroxide, tetracycline, azelaic acid and its derivatives, ethyl acetate, alantolactone, isoalantolactone, alkanet extract (alaninin), anise, arnica extract (helenalin acetate and 11, 13 dihydrohelenalin), aspidium extract (phloro, lucinol containing extract), barberry extract (berberine chloride), bay sweet extract, bayberry bark extract (myricitrin), benzalkonium chloride, benzethonium chloride, benzoic acid and its salts, benzoin, benzyl alcohol, blessed thistle, bletilla tuber, bloodroot, bois de rose oil, burdock, butyl paraben, cade oil, CAE (available from Ajinomoto located in Teaneck, NJ), cajeput oil, cangzhu, caraway oil, cascarilla bark (sold under the trade name ESSENTIAL OIL), cedarleaf oil, chamomille, chaparral, chlorophenesin, chlorxylenol, cinnamon oil, citronella oil, clove oil, dehydroacetic acid and its salts, dill seed oil, DOWICIL 200 (available from Dow Chemical located in Midland, MI), echinacea, elenolic acid, epimedium, ethyl paraben, FO-TI, galbanum, garden burnet, GERMALL 115 and GERMALL II (available from ISP-Sutton Labs located in Wayne, NJ), german chamomile oil, giant knotweed, GLYDANT (available from Lonza located in Fairlawn NJ), GLYDANT PLUS (available from Lonza located in Fairlawn, NJ), grapefruit seed oil, hexamidine diisethionate, hinokitiol, honey, honeysuckle flower, hops, immortelle, IODOPROPYNL BUTYL CARBAMIDE (available from Lonza located in Fairlawn, NJ), isobutyl paraben, isopropyl paraben, JM ACTICARE (available from Microbial Systems International located in Nottingham, UK), juniper berries, KATHON CG (available from Rohm and Haas located in Philadelphia, PA, USA), labdanum, lavender, lemon balm oil, lemon grass, methyl paraben, mint, mume, mustard, myrrh, neem seed oil, ortho phenyl phenol, OLIVE LEAF EXTRACT (available from Bio Botanica, located in Hauppauge, NY), parsley, patchouli oil, peony root, PHENONIP (available from Nipa Labs located in Wilmington, DE), phytosphingosine, pine needle oil, PLANSERVATIVE (available from Campo Research, located in Raffles Quay, Singapore), propyl paraben, purslane, quillaira, rhubarb, rose geranium oil, rosemary, sage, salicylic acid, sassafras, savory, sichuan lovage, sodium meta bisulfite, sodium sulfite, SOPHOLIANCE (available from Soliance located in Compiegne, France), sorbic acid and its salts, sphingosine, stevia, storax, tannic

acid, tea, tea tree oil (cajeput oil), thyme, triclosan, triclocarban, tropolone, turpentine, umbelliferone (antifungal), and yucca, or mixtures thereof. Further examples of anti-microbial and antifungal actives useful herein are described in WO98/18444.

Skin Soothing Agents: Skin soothing agents can be effective in preventing or treating inflammation of the skin. The soothing agent enhances the skin appearance benefits of the present invention, e.g., such agents contribute to a more uniform and acceptable skin tone or colour. Non-limiting examples of skin soothing agents include absinthium, acacia, aescin, alder buckthorn extract, allantoin, aloe, APT (available from Centerchem, located in Stamford, CT), arnica, astragalus, astragalus root extract, azulene, BAICALIN SR 15 (available from Barnet Products Dist. Located in Englewood, NJ), baikal skullcap, baizhu, balsam canada, bee pollen, BIOPHYTEX (available from Laboratories Serobiologiques, located in Somerville, NJ), bisabolol, black cohosh, black cohosh extract, blue cohosh, blue cohosh extract, boneset, borage, borage oil, borage seed oil, bromelain, calendula, calendula extract, CANADIAN WILLOWBARK EXTRACT (available from Fytokem), candelilla wax, cangzhu, canola phytosterols, capsicum, carboxypeptidase, celery seed, celery stem extract, CENTAURIUM (available from Sederma, located in Brooklyn, NY), centaury extract, chamazulene, chamomile, chamomile extract, chaparral, chaste tree, chaste tree extract, chickweed, chicory root, chicory root extract, chirata, chishao, colloidal oatmeal, comfrey, comfrey extract, CROMIST CM GLUCAN (available from Croda, located in Parsippany, NJ), darutoside, dehurian angelica, DEVIL'S CLAW (available from MMP located in Plainfield, NJ), divalent metals (such as magnesium, strontium, manganese), doggrass, dogwood, EASHAVE (available from Pentapharm, located in Basel, Switzerland), eleuthero, ELHIBIN (available from Pentapharm, located in Basel, Switzerland), ENTELINE 2 (available from Secma, located in Pontrieux, France), ephedra, epimedium, esculoside, evening primrose, eyebright, EXTRACT LE-100 (available from Sino Lion, located in World Trade Centre, NY), fangfeng, feverfew, ficin, forsythia fruit, ganoderma, gaoben, GATULINE A (available from Gattefosse, located in Saint Priest, France), gentian, germanium extract, ginkgo bilboa, ginkgo, ginseng extract, goldenseal, gorgonian extract, gotu kola, grape fruit extract, guaiac wood oil, guggal extract, helenalin esters, henna, honeysuckle flower, horehound extract, horsechestnut, horsetail, huzhang, hypericum, ichthyol, immortelle, ipecac, job's tears, jujube, kola extract, LANACHRYS 28 (available from Lana Tech, located in Paris, France), lemon oil, lianqiao, licorice root, ligusticum, ligustrum, lovage root, luffa, mace, magnolia flower, manjistha extract, margaspidin, margaspidin, matricin, MICROAT IRC (available from Nurture, located in Missoula, MT) mints, mistletoe, MODULENE (available from Seporga, located in Sophia Antipolis, France), mung bean extract, musk,

oat extract, orange, panthenol, papain, peony bark, peony root, PHYTOPLENOLIN (available from Bio Botanica, located in Hauppauge, NY), PREREGEN (available from Pentapharm, located in Basel, Switzerland), purslane, QUENCH T (available from Centerchem, located in Stamford, CT), quillaia, red sage, rehmannia, rhubarb, rosemary, rosmarinic acid, royal jelly, rue, rutin, sandalwood, sanqi, sarsaparilla, saw palmetto, SENSILINE (available from Silab, located in Brive, France), SIEGESBECKIA (available from Sederma, located in Brooklyn, NY), stearyl glycyrrhetinate, STIMUTEX (available from Pentapharm, located in Basel, Switzerland), storax, sweet birch oil, sweet woodruff, tagetes, tea extract, thyme extract, tienchi ginseng, tocopherol, tocopheryl acetate, triclosan, turmeric, urimei, ursolic acid, white pine bark, witch hazel, xinyi, yarrow, yeast extract, yucca, and mixtures thereof.

Sunscreening Agents: Examples of suitable sunscreening agents useful herein are described in WO98/18444, incorporated herein by reference. Further examples of sunscreens which are useful herein include diethanolamine p-methoxycinnamate, dioxybenzone, ethyl dihydroxypropyl PABA, glyceryl aminobenzoate, lawsone and dihydroxyacetone, menthyl anthranilate, methyl anthranilate, octyl dimethyl PABA, red petroleum, sulisobenzene, triethanolamine salicylate, and mixtures thereof.

Skin Barrier Repair Aids: Skin barrier repair aids are those skin care aids which can help repair and replenish the natural moisture barrier function of the epidermis. Suitable examples of skin barrier repair aids include brassicasterol, caffeine, campesterol, canola derived sterols, CERAMAX (available from Quest, located in Ashford, England), CERAMIDE 2 (available from Sederma, located in Brooklyn, NY), CERAMIDE HO3TM (available from Sederma, located in Brooklyn, NY), CERAMIDE II (available from Quest, located in Ashford, England), CERAMIDE III (available from Quest, located in Ashford, England), CERAMIDE IIIB (available from Cosmoferm, located in Delft, Netherlands), CERAMIDE IS 3773 (available from Laboratories Serobiologiques, located in Somerville, NJ), CERAMINOL (available from Inocosm, located in Chatenay Malabry, France), CERASOL (available from Pentapharm, located in Basel, Switzerland), CEPHALIP (available from Pentapharm, located in Basel, Switzerland), cholesterol, cholesterol hydroxystearate, cholesterol isostearate, 7-dehydrocholesterol, DERMATEIN BRC (available from Hormel, located in Austin, MN), DERMATEIN GSL (available from Hormel, located in Austin, MN), ELDEW CL 301 (available from Ajinomoto, located in Teaneck, NJ), ELDEW PS 203 (available from Ajinomoto, located in Teaneck, NJ), FITROBROSIDE (available from Pentapharm, located in Basel, Switzerland), GENEROL 122 (available from Henkel, located in Hoboken, NJ), glyceryl serine amide,

lactic acid, LACTOMIDE (available from Pentapharm, located in Basel, Switzerland), lanolin, lanolin alcohols, lanosterol, lauric acid n-laurylglucamide, lipoic acid, n-acetyl cysteine, serine, n-acetyl-L-serine, n-methyl-L-serine, NET STEROL-ISO (available from Barnet Products, located in Englewood, NJ), niacinamide, nicotinic acid and its esters, nicotinyl alcohol, palmitic acid, panthenol, panthetine, phosphodiesterase inhibitors, PHYTO/CER (available from Intergen, located in Purchaser, NY), PHYTOGLYCOLIPID MILLET EXTRACT (available from Barnet Products Distributer, located in Englewood, NJ), PHYTOSPHINGOSINE (available from Gist Brocades, located in King of Prussia, PA), PSENDOPILAGGRIN (available from Brooks Industries, located in South Plainfield, NJ), QUESTAMIDE H (available from Quest, located in Ashford, England), serine, stigmasterol, sitosterol, stigmastanol, soybean derived sterols, sphingosine, s-lactoyl glutathione, stearic acid, SUPER STEROL ESTERS (available from Croda, located in Parsippany, NJ), thioctic acid, THSC CERAMIDE OIL (available from Campo Research, located in Raffles Quay, Singapore), trimethyl glycine, tocopheryl nicotinate, vitamin D3 and analogs or derivatives thereof, and Y2 (available from Ocean Pharmaceutical), or mixtures thereof.

Anti-Wrinkle and Anti-Skin Atrophy Actives: Anti-wrinkle and anti-skin atrophy actives can be effective in replenishing or rejuvenating the epidermal and/or dermal layer. These actives generally provide these desirable skin care benefits by promoting or maintaining the natural process of desquamation and/or building skin matrix components (e.g., collagen and glycosaminoglycans). Non-limiting examples of anti-wrinkle and anti-skin atrophy actives include nicotinic acid and its esters, nicotinyl alcohol, estrogens and estrogenic compounds, or mixtures thereof. Further suitable anti-wrinkle and anti-skin atrophy actives useful herein are described in WO98/18444.

Skin Repair Actives: Non-limiting examples of skin repair actives include actein 27 - deoxyactein cimicifugoside (cimigосide), adapalene, tazarotene, ademethionine, adenosine, aletis extract, aloe derived lectins, 3-aminopropyl dihydrogen phosphate, AMADORINE (available from Barnet Products, located in Englewood, NJ), anise extracts, AOSINE (available from Secma, located in Pontrieux, France), arginine amino benzoate, ASC III (available from E. Merck, located in Darmstadt, Germany), ascorbic acid, ascorbyl palmitate, asiatic acid, asiaticosides, ARLAMOL GEO (available from ICI, located in Wilmington, DE), azaleic acid, benzoic acid derivatives, bertholletia extracts, betulinic acid, BIOCHANIN A, BIOPEPTIDE CL (available from Sederma, located in Brooklyn, NY) BIOPEPTIDE EL (available from Sederma, located in Brooklyn, NY), biotin, blackberry bark extract, blackberry lily extracts, black cohosh extract, blue cohosh

extract, butanoyl betulinic acid, catecholamines, chalcones, chaste tree extract, cis retinoic acid, citric acid esters, clover extracts, coenzyme Q10 (ubiquinone), coumestrol, CPC PEPTIDE (Barnet Products, located in Englewood, NJ), daidzein, dang gui extract, darutoside, debromo laurinterol, 1-decanoyl-glycero-phosphonic acid, dehydrocholesterol, dehydrodicreosol, dehydrodieugenol, dehydroepiandrosterone, DERMOLLECTINE (available from Sederma, located in Brooklyn, NY), dehydroascorbic acid, dehydroepiandrosterone sulfate, dianethole, 2,4-dihydroxybenzoic acid, diosgenin, disodium ascorbyl phosphate, dodecanedioic acid, EDERLINE (available from Seporga, located in Sophia Antipolis, France), ELESERYL SH (available from Laboratories Serobiologiques, located in Somerville, NJ), ENDONUCLEINE (available from Laboratories Serobiologiques, located in Somerville, NJ), equol, ergosterol, eriodictyol, estrogen and its derivatives, ethocyn, eythrobinic acid, farnesol, farnesyl acetate, fennel extract, FIBRASTIL (available from Sederma, located in Brooklyn, NY), FIBROSTIMULINES S AND P (available from Sederma, located in Brooklyn, NY), FIRMOGEN IS 8445 (available from Laboratories Serobiologiques, located in Somerville, NJ), flavonoids (especially flavanones such as unsubstituted flavanone and chalcones such as unsubstituted chalcone and monohydroxy and dihydroxy chalcones), formononetin, forsythia fruit extract, gallic acid esters, gamma amino butyric acid, GATULINE RC (available from Gattlefosse, located in Saint Priest, France), genistein, genisteine, genistic acid, gentisyl alcohol, ginkgo bilboa extracts, ginseng extracts, ginsenoside, RO, R₆₋₁, R₆₋₂, R₆₋₃, R_C, R_D, R_E, R_F, R_{F-2}, R_{G-1}, R_{G-2}, gluco pyranosyl-l-ascorbate, glutathione and its esters, glycitein, eptyloxy 4 salicylic acid, hesperitin, hexahydro curcumin, HMG-Coenzyme A Reductase Inhibitors, hops extracts, 11 hydroxy undecanoic acid, 10 hydroxy decanoic acid, 25-hydroxycholesterol, ISOFAVONE SG 10 (available from Barnet Products, located in Englewood, NJ), kinetin, L-2-oxo-thiazolidine-4-carboxylic acid esters, lactate dehydrogenase inhibitors, 1-lauryl-, lyso-phosphatidyl choline, lectins, LICHOCALCONE LR15 (available from Maruzen, located in Morristown, NJ), licorice extracts, lipoic acid, lumisterol, luteolin, magnesium ascorbyl phosphate, melatonin, melibiose, metalloproteinase inhibitors, methoprene, methoprenic acid, 4-methoxy salicylic acid, mevalonic acid, MPC COMPLEX (available from CLR, located in Berlin, Germany), N-acetyl cysteine, N-methyl serine, N-methyl taurine, N,N'-bis (lactyl) cysteamine, naringenin, neotigogenin, 5-octanoyl salicylic acid, O-desmethylangoiensin, oleanolic acid, pantethine, phenylalanine, photoanethone, phytic acid and its salts, piperidine, placental extracts, pratensein, pregnenolone, pregnenolone acetate, pregnenolone succinate, premarin, quillaic acid, raloxifene, REPAIR FACTOR 1 (available from Sederma, located in Brooklyn, NY), REPAIR FACTOR SPC (available

from Sederma, located in Brooklyn, NY), retinal, retinoates (esters of C₂-C₂₀ alcohols), retinol, retinyl acetate, retinyl glucuronate, retinyl linoleate, retinyl palmitate, retinyl propionate, REVITALIN BT (available from Pentapharm, located in Basel, Switzerland), s-carboxymethyl cysteine, salicylic acid, SEANAMINE FP (available from Laboratories Serobiologiques, located in Somerville, NJ), sodium ascorbyl phosphate, soya extracts, spleen extracts, tachysterol, taurine, tazarotene, thymulen, thymus extracts, thyroid hormones, tigogenin, tocopheryl retinoate, toxifolin, trans retinoic acid, traumatic acid, tricholine citrate, trifoside, uracil derivatives, ursolic acid, vitamin D₃ and its analogs, vitamin K, vitex extract, yam extract, yamogenin, and zeatin, or mixtures thereof.

Lipids: Examples of suitable lipids include cetyl ricinoleate, cholesterol hydroxystearate, cholesterol isostearate, CREMEROL (available from Amerchol, located in Edison, NJ), ELDEW C1301 (available from Ajinomoto, located in Teaneck, NJ), lanolin, MODULAN (available from Amerchol, located in Edison, NJ), OHLAN (available from Amerchol, located in Edison, NJ), petrolatum, phytantriol, and SUPER STEROL ESTERS (available from Croda, located in Parsippany, NJ), or mixtures thereof.

Skin Lightening Agents: Skin lightening agents can actually decrease the amount of melanin in the skin or provide such an effect by other mechanisms. Skin lightening agents suitable for use herein are described in EP-A-758,882 and EP-A-748,307, both of which are incorporated herein by reference. Further examples of skin lightening agents include adapalene, aloe extract, aminotyrosine, ammonium lactate, anethole derivatives, apple extract, arbutin, ascorbic acid, ascorbyl palmitate, azelaic acid, bamboo extract, bearberry extract, bletilla tuber, bupleurum falcatum extract, burnet extract, BURNET POWDER (available from Barnet Products, located in Englewood, NJ), butyl hydroxy anisole, butyl hydroxy toluene, chuanxiong, dang-gui, deoxyarbutin, 1,3-diphenyl propane derivatives, 2,5 dihydroxybenzoic acid and its derivatives, 2-(4-acetoxyphenyl)-1,3 dithane, 2-(4-hydroxyphenyl)-1,3 dithane, ellagic acid, escinol, estragole derivatives, esculoside, esculetin, FADEOUT (available from Pentapharm, located in Basel, Switzerland), fangfeng, fennel extract, gallic acid and its derivatives, ganoderma extract, gaoben, GATULINE WHITENING (available from Gattefosse, located in Saint Priest, France), genistic acid and its derivatives, gentisyl alcohol, glabridin and its derivatives, gluco pyranosyl-l-ascorbate, gluconic acid, glucosamine, glycolic acid, glycyrrhizinic acid, green tea extract, 4-hydroxy-5-methyl-3[2h]-furanone, hydroquinine, 4-hydroxyanisole and its derivatives, 4-hydroxy benzoic acid derivatives, hydroxycaprylic acid, inositol ascorbate, kojic acid, lactic acid, lemon extract, licorice extract, LICORICE P-TH (available from Barnet Products, located in Englewood, NJ), linoleic acid, magnesium ascorbyl phosphate, MELFADE (available from Pentapharm, located in Basel,

Switzerland), MELAWHITE (available from Pentapharm, located in Basel, Switzerland), morus alba extract, mulberry root extract, niacinamide, nicotinic acid and its esters, nicotinyl alcohol, 5-octanoyl salicylic acid, parsley extract, phellinus linteus extract, placenta extract, pyrogallol derivatives, retinoic acid, retinol, retinyl esters (acetate, propionate, palmitate, linoleate), 2,4 resorcinol derivatives, 3,5 resorcinol derivatives, rose fruit extract, rucinol, salicylic acid, song-yi extract, SOPHORA POWDER (available from Barnet Products, located in Englewood, NJ), 4-thioresorein, 3, 4, 5 trihydroxybenzyl derivatives, tranexamic acid, TYROSLAT 10,11 (available from Fytokem), vitamin D₃ and its analogs, yeast extract, or mixtures thereof.

Sebum Inhibitors: Sebum inhibitors can decrease the production of sebum in the sebaceous glands. Examples of suitable sebum inhibitors include aluminium hydroxy chloride, ASEBIOL (available from Laboratories Serobiologiques, located in Somerville, NJ), BIODERMINE (available from Sederma, located in Brooklyn, NY), climbazole, COMPLETECH MBAC-0S (available from Lipo, located in Peterson, NJ), corticosteroids, cucumber extracts, dehydroacetic acid and its salts, dichlorophenyl imidazoldioxolan, ketoconazole, LICHOCALCONE LR 15 (available from Maruzen), niacinamide, nicotinic acid and its esters, nicotinyl alcohol, phloretin, PHLOROGINE (available from Secma, located in Pontrieux, France), pyridoxine and derivatives thereof, s-carboxymethyl cysteine, SEPICONTROL AS, spironolactone, tioxolone, tocopherol, UNITRIENOL T27 (available from Unichem, located in Chicago IL), and ZINCIDONE (available from UCIB, located in Clifton, NJ), or mixtures thereof.

Sebum Stimulators: Sebum stimulators can increase the production of sebum by the sebaceous glands. Non-limiting examples of sebum stimulators include bryonolic acid, COMPLETECH MBAC-DS (available from Lipo, located in Paterson, NJ), dehydroepiandrosterone (also known as DHEA), orizanol, and mixtures thereof.

Skin Sensates: Non-limiting examples of suitable skin sensates for use herein include agents which impart a cool feel such as camphor, thymol, 1-menthol and derivatives thereof, eucalyptus, carboxamides; menthane ethers and menthane esters; and agents imparting a warm feel such as cayenne tincture, cayenne extract, cayenne powder, vanillylamide nonanoate, nicotinic acid derivatives (benzyl nicotinate, methyl nicotinate, phenyl nicotinate, etc.), capsaicin, nasturtium officinale extract, *Zanthoxylum piperitum* extract and ginger extract, or mixtures thereof.

Protease Inhibitors: Protease inhibitors are compounds which inhibit the process of proteolysis, that is, the splitting of proteins into smaller peptide fractions and amino acids. Examples of suitable protease inhibitors include A E COMPLEX (available from Barnet Products located in Englewood, NJ), ALE (available from Laboratoires Seporgia located

in Sophia Antipolis, France), allicin, AOSAIN (available from Secma Biotechnologies Marine located in Pontrieux, France), APROTININ (available from Pentapharm AG located in Basel, Switzerland), areca catechu extracts, BLUE ALGAE EXTRACT (available from Collaborative Labs Inc. located in East Setauket, NY), CENTAURIUM (available from Sederma located in Brooklyn, NY), CMST (available from Bioetica Inc. located in Portland, ME), DERMOPROTECTINE (available from Sederma located in Brooklyn, NY), DISACOSIDE HF 60 (available from Barnet Products located in Englewood, NJ), ELHIBIN (available from Pentapharm AG located in Basel, Switzerland), FLUID OUT COLLOID (available from Vegetech located in Glendale, CA), HYPOTAURINE (available from Sogo Pharmaceutical Co. Ltd located in Chirodaku Tokyo), IN CYTE HEATHER (available from Collaborative Labs Inc. located in East Setauket, NY), MICROMEROL (available from Collaborative Labs Inc. located in East Setauket, NY), PEFABLOC SP (available from Pentapharm AG located in Basel, Switzerland), SEPICONTROL AS (available from Seppic located in Paris, France), SIEGESBECKIA (available from Sederma located in Brooklyn, NY), SOPHORINE (available from Barnet Products located in Englewood, NJ), THIOTAIN (available from Barnet Products located in Englewood, NJ), and mixtures thereof.

Skin Tightening Agents: Non-limiting examples of skin tightening agents include BIO CARE SA (available from Amerchol located in Edison, NJ), egg albumen, FLEXAN 130 (available from National Starch located in Bridgewater, NJ), GATULINE LIFTING (available from Gattefosse located in Saint Priest, France), PENTACARE HP (available from Pentapharm AG located in Basel, Switzerland), VEGESERYL (available from Laboratories Serobioloques located in Somerville, NJ), and mixtures thereof.

Anti-Itch Ingredients: Non-limiting examples of anti-itch ingredients include STIMU-TEX (available from Pentapharm AG located in Basel, Switzerland), TAKANAL (available from Ikeda-Distributor, located in Tokyo, Japan), ICHTHYOL (available from International Sourcing-Distributor, located in Upper Saddle River, NJ), OXYGENATED GLYCERYL TRIESTERS (available from Laboratoires Seporgia located in Sophia Antipolis, France), and mixtures thereof.

Agents for Inhibiting Hair Growth: Non-limiting examples of suitable agents for inhibiting hair growth include 17 beta estradiol, adamantyguanidines, adamantylamidines, adenylosuccinate synthase inhibitors, anti angiogenic steroids, aspartate transcarbamylase inhibitors, betamethasone valerate, bisabolol, copper ions, curcuma extract, cyclooxygenase inhibitors, cysteine pathway inhibitors, dehydroacetic acid, dehydroepiandrosterone, diopyros leak extract, epidermal growth factor, epigallocatechin, essential fatty acids, evening primrose oil, gamma glutamyl transpeptidase inhibitors,

ginger oil, glucose metabolism inhibitors, glutamine metabolism inhibitors, glutathione, green tea extracts, heparin, KAPILANNE (available from International Sourcing Distributor, located in Upper Saddle River, NJ), L, 5 diaminopentanoic acid, L-asparagine synthase inhibitors, linoleic acid, lipoxygenase inhibitors, longa extract, mimosinamine dihydrochloride, mimosine, nitric oxide synthase inhibitors, non steroidal anti-inflammatories, ornithine decarboxylase inhibitors, ornithine aminotransferase inhibitors, panthenol, phorhetur, phosphodiesterase inhibitors, pleione extract, protein kinase C inhibitors, 5-alpha reductase inhibitors, sulfhydryl reactive compounds, tioxelone, transforming growth factor beta 1, urea, zinc ions, and mixtures thereof.

5 - Alpha Reductase Inhibitors: Non-limiting examples of 5-alpha reductase inhibitors include CLOVE 55 (available from Barnet Products Distributor located in Englewood, NJ), ethynylestradiol, genisteine, genistine, Licochalcone LR-15, saw palmetto extracts, SOPHORA EXTRACT (available from Maruzen located in Morristown, NJ), ZINCIDONE (available from UCIB, located in Clifton, NJ), and mixtures thereof.

Desquamation Enzyme Enhancers: These agents enhance the activity of endogenous desquamating enzymes. Non-limiting examples of desquamation enzyme enhancers include, N-methyl serine, serine, trimethyl glycine, and mixtures thereof.

Anti Glycation Agents: Anti-glycation agents prevent the sugar induced crosslinking of collagen. A suitable example of an anti-glycation agent includes AMADORINE (available from Barnet Products Distributor located in Englewood, NJ).

Preferred examples of benefit agents useful herein include those selected from the group consisting of salicylic acid, niacinamide, tocopheryl nicotinate, benzoyl peroxide, 3-hydroxy benzoic acid, flavonoids (e.g., flavanone, chalcone), farnesol, phytantriol, glycolic acid, lactic acid, 4-hydroxy benzoic acid, acetyl salicylic acid, 2-hydroxybutanoic acid, 2-hydroxypentanoic acid, 2-hydroxyhexanoic acid, cis-retinoic acid, trans-retinoic acid, retinol, retinyl esters (e.g., retinyl propionate), phytic acid, N-acetyl-L-cysteine, lipoic acid, tocopherol and its esters (e.g., tocopheryl acetate), azelaic acid, arachidonic acid, tetracycline, ibuprofen, naproxen, ketoprofen, hydrocortisone, acetaminophen, resorcinol, phenoxyethanol, phenoxypropanol, phenoxyisopropanol, 2,4,4'-trichloro-2'-hydroxy diphenyl ether, 3,4,4'-trichlorocarbanilide, octopirox, lidocaine hydrochloride, clotrimazole, miconazole, ketoconazole, neomycin sulfate, theophylline, and mixtures thereof.

For cosmetic methods of treatment of the skin, hair or nails, the benefit agent is preferably selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, skin repair actives, skin barrier repair aids, skin

lightening agents, skin sensates, skin soothing agents, lipids, sebum inhibitors, sebum stimulators, sunscreens agents, protease inhibitors, skin tightening agents, anti-itch ingredients, and desquamation enzyme enhancers, or mixtures thereof.

Humectants

Preferred pre-formed, sheet devices comprise at least one humectant.

Humectants can be added to achieve a plasticising effect and to increase the moisturising characteristics of the pre-formed, sheet device when applied to the target surface. Certain humectants such as hexylene glycol may also contribute to the antibacterial properties and characteristics of a pre-formed, sheet device of the present invention. Further, without wishing to be limited by theory, it is thought that incorporating humectants into the pre-formed, sheet devices of the present invention, increases the stability of the devices such that they are less likely to undergo decomposition under extreme temperature conditions.

In general, the pre-formed, sheet devices of the present invention comprise from about 1.0% to about 45%, preferably from about 5% to about 40%, more preferably from about 10% to about 30% by weight of a humectant.

Suitable humectants for use in the present invention are described in WO98/22085, WO98/18444 and WO97/01326, all of which are incorporated herein by reference. Further suitable humectants include amino acids and derivatives thereof such as proline and arginine aspartate, 1,3-butylene glycol, propylene glycol and water and codium tomentosum extract, collagen amino acids or peptides, creatinine, diglycerol, biosaccharide gum-1, glucamine salts, glucuronic acid salts, glutamic acid salts, polyethylene glycol ethers of glycerin (e.g. glycereth 20) glycerin, glycerol monopropoxylate, glycogen, hexylene glycol, honey, and extracts or derivatives thereof, hydrogenated starch hydrolysates, hydrolyzed mucopolysaccharides, inositol, keratin amino acids, LAREX A-200 (available from Larex), glycosaminoglycans, methoxy PEG 10, methyl gluceth-10 and -20 (both commercially available from Amerchol located in Edison, NJ), methyl glucose, 3-methyl-1,3-butandiol, N-acetyl glucosamine salts, panthenol, polyethylene glycol and derivatives thereof (such as PEG 15 butanediol, PEG 4, PEG 5 pentaerythritol, PEG 6, PEG 8, PEG 9), pentaerythritol, 1,2 pentanediol, PPG-1 glyceryl ether, PPG-9, 2-pyrrolidone-5-carboxylic acid and its salts such as glyceryl pca, saccharide isomerate, SEACARE (available from Secma), sericin, silk amino acids, sodium acetylhyaluronate, sodium hyaluronate, sodium poly-aspartate, sodium polyglutamate, sorbeth 20, sorbeth 6, sugar and sugar alcohols and derivatives thereof such as glucose, mannose and polyglycerol sorbitol, trehalose, triglycerol, trimethylpropane, tris (hydroxymethyl) amino methane salts, and yeast extract, or mixtures thereof.

Preferably, the humectants for use herein are selected from glycerine, butylene glycol, hexylene glycol, panthenol and polyethylene glycol and derivatives thereof, or mixtures thereof.

Emulsifiers/Surfactants

The pre-formed, sheet devices of the present invention can also optionally comprise one or more surfactants and/or emulsifiers. Emulsifiers and/or surfactants, generally help to disperse and suspend the discontinuous phase within the continuous phase. A surfactant may also be useful if the product is intended for skin cleansing. For convenience hereinafter emulsifiers will be referred to under the term 'surfactants', thus 'surfactant(s)' will be used to refer to surface active agents whether used as emulsifiers or for other surfactant purposes such as skin cleansing. Known or conventional surfactants can be used in the composition, provided that the selected agent is chemically and physically compatible with essential components of the composition, and provides the desired characteristics. Suitable surfactants include silicone materials, non-silicone materials, and mixtures thereof.

The compositions of the present invention preferably comprise from about 0.01% to about 15% of a surfactant or mixture of surfactants. The exact surfactant or surfactant mixture chosen will depend upon the pH of the composition and the other components present.

Preferred surfactants are nonionic. Among the nonionic surfactants that are useful herein are the condensation products of alkylene oxides with fatty acids (i.e. alkylene oxide esters of fatty acids). These materials have the general formula $\text{RCO}(\text{X})_n\text{OH}$ wherein R is a C_{10-30} alkyl group, X is $-\text{OCH}_2\text{CH}_2-$ (i.e. derived from ethylene glycol or oxide) or $-\text{OCH}_2\text{CHCH}_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 200. Other nonionic surfactants are the condensation products of alkylene oxides with 2 moles of fatty acids (i.e. alkylene oxide diesters of fatty acids). These materials have the general formula $\text{RCO}(\text{X})_n\text{OOCR}$ wherein R is a C_{10-30} alkyl group, X is $-\text{OCH}_2\text{CH}_2-$ (i.e. derived from ethylene glycol or oxide) or $-\text{OCH}_2\text{CHCH}_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 100. Other nonionic surfactants are the condensation products of alkylene oxides with fatty alcohols (i.e. alkylene oxide ethers of fatty alcohols). These materials have the general formula $\text{R}(\text{X})_n\text{OR}'$ wherein R is a C_{10-30} aliphatic group, X is $-\text{OCH}_2\text{CH}_2-$ (i.e. derived from ethylene glycol or oxide) or $-\text{OCH}_2\text{CHCH}_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 100 and R' is H or a C_{10-30} aliphatic group, examples of which include PEG 40 Hydrogenated Castor Oil, available

under the trade name "Cremophor RH 40" from BASF (Parsippany, NJ, USA); PEG 60 Hydrogenated Castor Oil, available under the trade name "Cremophor RH 60" from BASF (Parsippany, NJ, USA); isoceteth-20, available under the trade name "Arlasolve 200" from ICI (Wilmington, MA, USA); and oleth-20, available under the trade name "Volpo N20" from Croda Chemicals Ltd. (Goole, North Humberside, England). Still other nonionic surfactants are the condensation products of alkylene oxides with both fatty acids and fatty alcohols [i.e. wherein the polyalkylene oxide portion is esterified on one end with a fatty acid and etherified (i.e. connected via an ether linkage) on the other end with a fatty alcohol]. These materials have the general formula $\text{RCO}(\text{X})_n\text{OR}'$ wherein R and R' are C_{10-30} alkyl groups, X is $-\text{OCH}_2\text{CH}_2$ (i.e. derived from ethylene glycol or oxide) or $-\text{OCH}_2\text{CHCH}_3$ - (derived from propylene glycol or oxide), and n is an integer from about 6 to about 100, examples of which include ceteth-6, ceteth-10, ceteth-12, cetareth-6, cetareth-10, cetareth-12, steareth-6, steareth-10, steareth-12, PEG-6 stearate, PEG-10 stearate, PEG-100 stearate, PEG-12 stearate, PEG-20 glyceryl stearate, PEG-80 glyceryl tallowate, PEG-10 glyceryl stearate, PEG-30 glyceryl cocoate, PEG-80 glyceryl cocoate, PEG-200 glyceryl tallowate, PEG-8 dilaurate, PEG-10 distearate, and mixtures thereof.

Other nonionic surfactants that are useful herein are alkyl glucosides and alkyl polyglucosides which are described in more detail in WO98/18444, incorporated herein by reference.

Still other useful nonionic surfactants include polyhydroxy fatty acid amide surfactants, which are described in more detail in WO98/04241.

Other nonionic surfactants suitable for use herein include sugar esters and polyesters, alkoxyated sugar esters and polyesters, C_1 - C_{30} fatty acid esters of C_1 - C_{30} fatty alcohols, alkoxyated derivatives of C_1 - C_{30} fatty acid esters of C_1 - C_{30} fatty alcohols, alkoxyated ethers of C_1 - C_{30} fatty alcohols, polyglyceryl esters of C_1 - C_{30} fatty acids, C_1 - C_{30} esters of polyols, C_1 - C_{30} ethers of polyols, alkyl phosphates, polyoxyalkylene fatty ether phosphates, fatty acid amides, acyl lactylates, and mixtures thereof. Examples of these non-silicon-containing surfactants include: polysorbate 20, polyethylene glycol 5 soya sterol, steareth-20, cetareth-20, PPG-2 methyl glucose ether distearate, polysorbate 80; polysorbate 60, available under the trade name "Tween 60" from ICI (Wilmington, MA, USA); glyceryl stearate, sorbitan monolaurate, polyoxyethylene 4 lauryl ether sodium stearate, polyglyceryl-4 isostearate, hexyl laurate, PPG-2 methyl glucose ether distearate, and mixtures thereof.

Preferred among the nonionic surfactants are those selected from the group consisting of cetareth-12, sucrose cocoate, steareth-100, polysorbate 60, PEG-60 Hydrogenated Castor Oil, isoceteth-20, oleth-20, PEG-100 stearate, and mixtures thereof.

Other suitable emulsifiers for use herein are polyoxypropylene, polyoxyethylene ethers of fatty alcohols. These materials have the general formula $R(\text{CH}_2\text{CHCH}_3\text{O})_x(\text{CH}_2\text{CH}_2\text{O})_y\text{-H}$, wherein R is an $\text{OC}_{10}\text{-C}_{30}$ alkyl group or $\text{C}_{10}\text{-C}_{30}$ alkyl group, x has an average value from 1 to 20 and y has an average value from 1 to 30, examples of which include PPG-6-Decyltetradeceth-30, available under the trade name "Pen 4630" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); PPG-6-Decyltetradeceth-20, available under the trade name "Pen 4620" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); and PPG-5-Ceteth-20, available under the trade name "Procetyl AWS" from Croda Chemicals Ltd. (Goole, North Humberside, England).

Another emulsifier useful herein are fatty acid ester blends based on a mixture of sorbitan or sorbitol fatty acid ester and sucrose fatty acid ester, as described in more detail in WO98/22085, incorporated by reference herein.

The hydrophilic surfactants useful herein can alternatively or additionally include any of a wide variety of cationic, anionic, zwitterionic, and amphoteric surfactants such as are known in the art. See, e.g., McCutcheon's, Detergents and Emulsifiers, North American Edition (1986), published by Allured Publishing Corporation; US-A-5,011,681 to Ciotti et al., issued April 30, 1991; US-A-4,421,769 to Dixon et al., issued December 20, 1983; and US-A-3,755,560 to Dickert et al., issued August 28, 1973; these four references are incorporated herein by reference in their entirety.

A wide variety of cationic surfactants are useful herein. Suitable cationic surfactants for use herein are disclosed in WO98/18444.

A wide variety of anionic surfactants are also useful herein. See, e.g., US-A-3,929,678, to Laughlin et al., issued December 30, 1975, which is incorporated herein by reference in its entirety. Exemplary anionic surfactants include the alkoyl isethionates (e.g., C_{12} - C_{30}), alkyl and alkyl ether sulfates and salts thereof, alkyl and alkyl ether phosphates and salts thereof, alkyl methyl taurates (e.g., C_{12} - C_{30}), and soaps (e.g., alkali metal salts, e.g., sodium or potassium salts) of fatty acids.

Amphoteric and zwitterionic surfactants are also useful herein. Examples of amphoteric and zwitterionic surfactants which can be used in the compositions of the present invention are those which are broadly described as derivatives of aliphatic secondary and

tertiary amines in which the aliphatic radical can be straight or branched chain and wherein one of the aliphatic substituents contains from about 8 to about 22 carbon atoms (preferably C₈ - C₁₈) and one contains an anionic water solubilising group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Examples are alkyl imino acetates, and iminodialkanoates and aminoalkanoates, imidazolinium and ammonium derivatives. Other suitable amphoteric and zwitterionic surfactants are those selected from the group consisting of betaines, sultaines, hydroxysultaines, alkyl sarcosinates (e.g., C₁₂ - C₃₀), and alkanoyl sarcosinates.

The pre-formed, sheet devices of the present invention may optionally contain a silicone containing emulsifier or surfactant. A wide variety of silicone emulsifiers are useful herein. These silicone emulsifiers are typically organically modified organopolysiloxanes, also known to those skilled in the art as silicone surfactants. Useful silicone emulsifiers include dimethicone copolyols. These materials are polydimethyl siloxanes which have been modified to include polyether side chains such as polyethylene oxide chains, polypropylene oxide chains, mixtures of these chains, and polyether chains containing moieties derived from both ethylene oxide and propylene oxide. Other examples include alkyl-modified dimethicone copolyols, i.e., compounds which contain C₂-C₃₀ pendant side chains. Still other useful dimethicone copolyols include materials having various cationic, anionic, amphoteric, and zwitterionic pendant moieties.

Oil Soluble Conditioning Agents

The present invention can also optionally comprise oil soluble conditioning agents. Examples of conditioning agents useful as oil soluble conditioning agents include mineral oil, petrolatum, C₇-C₄₀ branched chain hydrocarbons, C₁-C₃₀ alcohol esters of C₁-C₃₀ carboxylic acids, C₁-C₃₀ alcohol esters of C₂-C₃₀ dicarboxylic acids, monoglycerides of C₁-C₃₀ carboxylic acids, diglycerides of C₁-C₃₀ carboxylic acids, triglycerides of C₁-C₃₀ carboxylic acids, ethylene glycol monoesters of C₁-C₃₀ carboxylic acids, ethylene glycol diesters of C₁-C₃₀ carboxylic acids, propylene glycol monoesters of C₁-C₃₀ carboxylic acids, propylene glycol diesters of C₁-C₃₀ carboxylic acids, C₁-C₃₀ carboxylic acid monoesters and polyesters of sugars, polydialkylsiloxanes, polydiarylsiloxanes, polyalkarylsiloxanes, cyclomethicones having 3 to 9 silicon atoms, vegetable oils, hydrogenated vegetable oils, polypropylene glycol C₄-C₂₀ alkyl ethers, di C₈-C₃₀ alkyl ethers, and mixtures thereof.

These agents are described in more detail in WO98/18444, which is incorporated herein by reference.

Thickening Polymers

The pre-formed, sheet devices of the present invention can also comprise thickening polymers, preferably from about 0.01% to about 5%, more preferably from about 0.05 to about 3%, and most preferably from about 0.1% to about 2%, by weight of a thickening polymer.

Thickening polymers may be combined with the polysaccharide mixture described herein to modify the properties of said gels. The thickening polymers may be chemically or physically cross-linked or employed in the polysaccharide mixture *per se*.

Suitable thickening polymers useful herein include polyvinyl pyrrolidones, poly-2-ethyl-2-oxazoline, polyvinyl alcohol, polyethylene oxide, polyvinyl ethers, copolymers of polyvinylethers and polyvinylpyrrolidone and derivatives thereof, methyl vinyl ether and maleic anhydride, copolymers of ethylene and maleic anhydride; acrylic acid based polymers or derivatives thereof such as polyacrylic acids; polyethylene glycol monomethacrylate, polydimethyl acrylamide, salts of polyacrylic acid such as ammonium polyacrylate and sodium polyacrylate; and copolymers of acrylamide and N,N¹-methylene bisacrylamide and polyacrylamide; and polyacrylamide.

Additional Polysaccharides

The pre-formed, sheet devices of the present invention can also comprise additional polysaccharides. As herein before described, the sheet device of the present invention contains less than 10% total polysaccharide (by dry weight). The additional polysaccharides, if present, contribute to the total dry weight of the polysaccharides comprising the device.

Suitable additional polysaccharides include galactomannans; fermentation polysaccharides or derivatives thereof such as gellan gum, xanthan gum, natto gum, pullulan, rhamsan gum, curdlan, succinoglycan, welan gum, dextran, sclerotium gum; brown seaweed polysaccharides such as algin, alginic acid, alginate salts (such as calcium, potassium, aluminium or sodium) and propylene glycol alginate; extracts of marine invertebrates such as chitosan and hydroxypropyl chitosan and derivatives; starch or derivatives thereof; natural fruit extracts such as pectin and arabian; natural plant exudates such as karaya gum, tragacanth gum, arabic gum, tamarind gum, and ghatty gum; and resinous gums such as shellac gum, damar gum, copal gum and rosin gum; or mixtures thereof.

Further suitable examples of additional polysaccharides useful herein are cellulose and derivatives thereof as described in WO97/28785, incorporated herein by reference.

Other Optional Ingredients

The compositions of the present invention can comprise a wide range of other optional components. These additional components should be pharmaceutically acceptable. The CTFA Cosmetic Ingredient Handbook: Second Edition, 1992, which is incorporated by reference herein in its entirety, describes a wide variety of non-limiting cosmetic and pharmaceutical ingredients commonly used in the cosmetic industry, which are suitable for use in the compositions of the present invention. Non-limiting examples of functional classes of ingredients are described at page 537 of this reference. Examples of these and other functional classes include: abrasives, absorbents, antibiotics, anticaking agents, anti-dandruff agents, anti-perspirant agents, antioxidants, vitamins, biological additives, bleach, bleach activators, brighteners, builders, buffering agents, chelating agents, chemical additives, colorants, cosmetics, cleansers, cosmetic astringents, cosmetic biocides, denaturants, dental treatments, deodorants, desquamation actives, depilatories, drug astringents, dyes, dye transfer agents, enzymes, external analgesics, flavors, film formers, fragrance components, insect repellants, mildewcides, opacifying agents, oxidative dyes, oxidising agents, pest control ingredients, pH adjusters, pH buffers, pharmaceutical actives, plasticizers, preservatives, radical scavengers, skin, hair or nail bleaching agents, skin, hair or nail conditioners, skin, hair or nail penetration enhancers, stabilisers, surface conditioners, reducing agents, temperature depressors, and warmth generators.

Also useful herein are aesthetic components such as colorings, essential oils, and skin healing agents.

Other optional materials herein include pigments. Pigments suitable for use in the compositions of the present invention can be organic and/or inorganic. Also included within the term pigment are materials having a low colour or lustre such as matte finishing agents, and also light scattering agents. Examples of suitable pigments are iron oxides, acyglutamate iron oxides, titanium dioxide, ultramarine blue, D&C dyes, carmine, and mixtures thereof. Depending upon the type of composition, a mixture of pigments will normally be used.

The pH of the sheet devices herein is preferably from about 3 to about 9, more preferably from about 4 to about 8.

The pre-formed, sheet devices of the present invention are patches or masks having a size and shape adapted to conform to the desired target area. The exact size and shape will depend upon the intended use and product characteristics. The pre-formed, sheet devices herein are suitable for topical application to the nails or cuticles, the hair or scalp, a human face or part thereof, legs, hands, arms, feet, or human torso. The devices herein may be for example, square, circular, rectangular, oval, or other shapes which are composites of these such as shapes that could be described as "semi-circle", "donut", or others. The surface area for devices shaped to fit the face have a surface area ranging from 0.25 cm² to about 500 cm², preferably from about 1 cm² to about 400 cm². The devices herein have a thickness of from about 0.5 mm to about 20 mm, preferably from about 1 mm to about 5 mm.

The pre-formed, sheet devices of the present invention may also be made and used in the form of handwear, footwear, or a body wrap. Typically, the handwear will comprise a glove for the hand or any portion thereof, and the footwear will comprise a sock for the foot or any portion thereof. As used herein, the term "glove" is meant to be inclusive of "mitten." Preferably, the handwear comprises a glove body comprising a middle section, from one to four finger receptacles connected with the middle section, a thumb receptacle connected with the middle section, a palm side and an opposite back side. Preferably, the footwear comprises a sock body forming a tubular foot portion having a closed end and an open end. The inventive devices may also be made or used in the form of a body wrap. The body wrap is wrapped radially around any body part having a longitudinal axis. Its ends may communicate with each other, or its length may be shortened so as to only wrap partially around. In either case, the wraps should exhibit excellent conformity to the shape of the body part. Typically, such body parts will include the user's back, upper arm, lower arm, upper leg, lower leg, neck, and torso.

Following application of the device, it may be left on the target area for about 3 hours, preferably about 1 hour, more preferably less than 15 minutes. The pre-formed, sheet device can then be removed all in one piece.

Depending on the benefit agent (or benefit agents) contained therein, the pre-formed, sheet devices of the present invention may have at least one of the following uses; hydrating the skin, hair or nails, smoothing fine lines and wrinkles; cosmetically treating acne; firming the skin; strengthening; softening; exfoliating; improving and/or evening skin tone and/or texture; skin, hair or nail lightening; conditioning the skin or hair; tanning; reducing the appearance of pores; absorbing or controlling secretions; protecting and/or soothing the skin, hair or nails, muscles, aches or pains; reducing puffiness, and/or

dark circles; stimulating wound healing; warming, refreshing or cooling the skin; relieving inflammation; brightening the complexion; decongesting; reducing swelling; treating dermatological conditions; cushioning; purifying; fragrancng; reducing bacterial or micro-organism growth; healing; repelling insects; removing unwanted hair, dirt, or make-up; and colouring or bleaching the target area to which the device is applied. Preferably, the pre-formed, sheet devices herein are used for hydrating the skin, hair or nails; smoothing fine lines and wrinkles; and improving and/or evening skin tone and/or texture.

Methods

Exudate Release Test

The amount of syneresis from a pre-formed, sheet device of the present invention is measured on the polysaccharide gel mixture comprising the device via an exudate release test.

Data on exudate release from gels referenced herein were generated by the following method. A gel formulation of interest is prepared as described below. While still a hot liquid ($>80^{\circ}\text{C}$), nine grams (± 0.1 g) is poured into a 91 mm diameter shallow receptacle, e.g. the lid of a Falcon-1029 Petri dish. This receptacle is hermetically sealed to reduce evaporative losses. The gel is allowed to solidify undisturbed with cooling to room temperature. The gel is stored at room temperature overnight before readings are taken. The covering is removed and the receptacle with sample tared ($\pm 0.005\text{g}$). Three pieces of filter paper (9.0 cm Whatman-114 Wet Strengthened) are stacked on the flat gel surface. A 9.0 cm diameter flat-bottomed weight of 200 g is placed on the filter paper to ensure close contact with the gel surface. After one minute the weight is removed and filter paper gently peeled away from the gel. The paper should impart a clearly visible matte surface to the gel, which confirms good contact by the filter paper. The sample is reweighed and mass loss calculated by difference. This is reported as grams of exudate released for the 9cm diameter gel disc described above.

Gel Compressive Rupture Test

The mechanical properties of the pre-formed, sheet devices of the present invention are measured via compressive failure testing of the gel. The parameters of interest are the gel strength (measured via the compressive force required to rupture a moulded cylinder of gel) and the gel flexibility (measured via the extent of gel compression at the point of rupture). A more detailed description of the test method follows.

Compressive failure testing is performed using a Stable Micro Systems (SMS) Texture Analyser (TA), model TA-XT2i available from Stable Micro Systems Ltd (Godalming, Surrey, UK). The system is controlled through SMS's Texture Expert Exceed software (version 2.03) running within Windows-98. A 100 mm diameter Aluminum compression plate (P-100 probe) is attached to a 50 Kg load cell. This is mounted within the TA Probe Carrier, the extended arm whose vertical travel is under computer control.

To create test samples, a gel formulation of interest is prepared as described below. Gel discs of a precise cylindrical-solid shape (26 mm diameter by 12 mm depth) are formed in moulds. The moulds with sample are hermetically sealed against evaporation during storage. These gel discs are stored at ambient temperature overnight. Each gel disc is removed from its mould just prior to testing and visually inspected for defects. Any gel discs with defects (e.g. trapped air bubbles) are discarded as these defects may impact the measured mechanical properties. The non-defective gel disc is then centered under the P-100 compression plate.

The Texture Expert Exceed software is set-up in Force / Compressive mode. The compression plate is pre-set to a starting height of 12.0 mm. Its rate of descent is set to 0.8 mm/second and total travel distance set to 10.8 mm (i.e. measurement stops when the gel disc is compressed by 90% of its original height). Data is automatically collected on force and position of the compression plate at the rate of 200 pps (points per second). The software is pre-set to mark compression plate position at the maximum force achieved. This maximum force is the rupture strength, that is, the force required to rupture the gel disc. The distance travelled by the plate from its original starting height to the point of gel rupture represents the extent of deformation of the gel. The maximum force at the point of rupture is averaged across samples (typically 5 replicates) and reported in Newtons.

The uni-axial deformation (compression) at the gel's point of rupture is expressed as a percent of its original moulded height, i.e.

$$\% \text{ Compression} = \frac{\text{distance travelled by plate (measured in mm) at maximum force}}{12 \text{ mm (original moulded sample height)}} \times 100$$

If gel rupture has not occurred by the end of the 10.8 mm stroke, (i.e. 90% compression), the gel is classified as 'non-rupturing' under these test conditions.

The invention is illustrated by the following examples.

Ingredient	E.G. 1 %w/w	E.G. 2 %w/w	E.G. 3 %w/w
Agar	-	0.6	-
Agarose	-	0.3	0.7
Kappa-Carrageenan	0.5	-	-
Locust Bean Gum	-	0.1	0.3
Konjac Mannan	0.5	0.2	0.2
Xanthan Gum	-	0.1	-
Glycerin	20.0	15.0	20.0
Butylene Glycol	5.0	-	5.0
Panthenol	1.0	3.0	-
Niacinamide	10.0	-	-
Polysorbate 60	-	0.08	-
Dimethicone Copolyol	0.02	-	-
Benzyl Alcohol	-	0.3	-
Ethyl Paraben	0.2	0.1	0.15
Propyl Paraben	-	0.05	-
Disodium EDTA	0.1	-	0.1
Water	to 100	to 100	to 100
Exudate Release/g	1.32	0.76	1.04
Force To Rupture/N	No Rupture	78	106
% Compression	No Rupture	58	59
<i>Substrate</i>	-	<i>Paper¹</i>	-

1. "Kimwipes EX-L" available from Kimberley-Clark Corp., Roswell, GA, USA.

The polysaccharide gums are mixed with water to form a uniform dispersion (this can be facilitated by pre-dispersing the polysaccharides in a non-solvent e.g. polyhydric alcohol) and any additional components are added. The mixture is heated with stirring to a first temperature above the gel point of the mixture (ca. 90°C) to fully hydrate the polysaccharide gums. The liquid gel is then dispensed into a suitably shaped mould. Preferably, the liquid gel is dispensed via injection moulding. This eliminates any defects which may be introduced by cutting the gel and so improves the robustness of the device. Injection moulding also allows devices to be readily formed with varying regions of thickness and other structural features. Alternatively, the liquid gel may be cast into a sheet. The liquid gel is then cooled to a second temperature cooler than the first temperature at or below the gel point of the mixture (e.g. ambient temperature) to set up the gel structure. The device may then be removed from the mould or appropriately

shaped patches may be cut from the gel sheet. The devices herein are then packaged into materials which have low water vapour permeability to minimise drying out of the device during storage. Suitable packaging for devices herein include sachets or sealed trays. If the device is packaged in a sachet, it is preferably protected prior to use. This protection can be provided by a release liner such as a plastic film, which provides easy release for the device.

If a substrate is to be used, (Example 2) this may be placed in the suitably shaped mould prior to dispensing the gel or it may be placed on the surface of the liquid gel during the cooling stage.

In some compositions, metal ions (e.g. Ca^{2+} , K^+) may be included in the formulation to increase the gel strength of the device. In this case, the metal ions are added in the form of an aqueous solution and are stirred into the hydrated liquid gel as the final addition to the mixture.

The above method may be modified as necessary depending on the nature of any additional components. For example, if non-aqueous components are present, the liquid gel may be homogenised immediately prior to moulding or casting to ensure dispersion of the non-aqueous components. Similarly, if heat sensitive ingredients are incorporated, the formulation should be cooled to an appropriate temperature (dependent on the ingredient) after the gum hydration step and the heat sensitive ingredient added at this stage.

The liquid gel may be de-gassed, e.g. by vacuum, to remove air bubbles dispersed within the liquid. This de-gassing step, if followed, would be the final step immediately prior to dispensing the liquid gel.

As shown above, the pre-formed, sheet devices have a desirable amount of syneresis, strength or flexibility.

CLAIMS

1. A pre-formed, sheet device comprising;
 - (a) less than 10% of a polysaccharide mixture consisting of at least one red seaweed polysaccharide and at least one glucomannan; and;
 - (b) from about 30% to about 99.5% of waterwherein the device comprises less than 10% total polysaccharide.
2. A pre-formed, sheet device according to Claim 1 which comprises less than 5% of the polysaccharide mixture.
3. A pre-formed, sheet device according any of Claims 1 to 2 wherein the ratio of red seaweed polysaccharide to glucomannan is from about 5:1 to about 1:5.
4. A pre-formed, sheet device according any of Claims 1 to 3 wherein the ratio of red seaweed polysaccharide to glucomannan is from about 2:1 to about 1:2.
5. A pre-formed, sheet device according to any of Claims 1 to 4 wherein the red seaweed polysaccharide is selected from kappa-carrageenan and furcellaran, or mixtures thereof.
6. A pre-formed, sheet device according to any of Claims 1 to 5 wherein the glucomannan is konjac mannan.
7. A pre-formed, sheet device according to any of Claims 1 to 6 further comprising a benefit agent selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, skin repair actives, skin barrier repair aids, skin lightening agents, skin sensates, skin soothing agents, anti-microbial and anti-fungal actives, lipids, sebum inhibitors, sebum stimulators, sunscreens agents, antiseptics, topical anaesthetics, steroids, non-steroidal anti-inflammatory agents, protease inhibitors, skin tightening agents, anti-itch ingredients, agents for inhibiting hair growth, 5-alpha reductase inhibitors, anti-glycation agents, and desquamation enzyme enhancers, or mixtures thereof.
8. A pre-formed, sheet device according to any of Claims 1 to 6 further comprising a benefit agent selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, skin repair actives, skin barrier repair aids, skin lightening agents, skin sensates, skin soothing agents, lipids, sebum inhibitors, sebum stimulators, sunscreens agents, protease inhibitors, skin

tightening agents, anti-itch ingredients, and desquamation enzyme enhancers, or mixtures thereof.

9. A pre-formed, sheet device according to any of Claims 1 to 8 which further comprises a substrate.
10. A pre-formed, sheet device according to any of Claims 1 to 9 wherein the pre-formed, sheet device further comprises at least one humectant.
11. A pre-formed, sheet device according to any of Claims 1 to 10 in the form of a mask or patch having a size and shape adapted to conform to the nails or cuticles, the hair or scalp, a human face or part thereof, legs, arms, hands, feet or human torso.
12. A cosmetic method of treatment comprising applying to the skin, hair or nails a pre-formed, sheet device according to any of Claims 1 to 6, 8, 9, 10 or 11.
13. Use of a polysaccharide mixture consisting of at least one red seaweed polysaccharide and at least one glucomannan, for improving the strength, syneresis or flexibility of a pre-formed, sheet device comprising water.
14. A pre-formed, sheet device according to any of Claims 1 to 10, in a form selected from the group consisting of: handwear; footwear; and body wrap.

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(54) Title: PRE-FORMED, SELF-ADHESIVE SHEET DEVICES SUITABLE FOR TOPICAL APPLICATION

(57) Abstract: A pre-formed, sheet device comprising; (a) less than 10 % of a polysaccharide mixture consisting of at least one red seaweed polysaccharide and at least one glucomannan; and (b) from about 30 % to about 99.5 % of water wherein the device comprises less than 10 % total polysaccharide. The pre-formed, sheet devices of the invention are suitable for topical application and display desirable amounts of syneresis and/or improved mechanical properties such as strength or flexibility, as well as excellent moisturisation, hydration and cooling benefits. Further, the devices of the present invention are easy to handle, unobtrusive and conform to the contours of a target surface when applied.



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A. CLASSIFICATION OF SUBJECT MATTER
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☒ Further documents are listed in the continuation of box C.

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